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UNCLAS SANTIAGO 000188

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SUBJECT: CHILE - INPUT FOR 2009 SPECIAL 301 REVIEW

REF: A) STATE 8410 B) 08 SANTIAGO 1045 C) 08 SANTIAGO 1088

¶1. (SBU) SUMMARY: Post recommends Chile remain on the 2009 Special 301 Priority Watch List (PWL) for a third year. There was less progress on intellectual property rights (IPR) than hoped for in ¶2008. Post has identified four priority areas for GOC action: anti-piracy and counterfeiting, data protection and patent linkage, copyrights/trademarks, and supporting legislation. The GOC made progress in some areas, such as approval of the Patent Cooperation Treaty (PCT). Chile agreed to a review of its IPR commitments under the U.S.-Chile Free Trade Agreement (FTA) at the December 2008 Free Trade Commission. The PWL remains an important tool for motivating the GOC to make progress on IPR. END SUMMARY.

BACKGROUND: Chile's History on the PWL  
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¶2. (SBU) In 2004, the U.S.-Chile FTA entered into force. Chile was the subject of an Out-of-Cycle Review by the Office of the U.S. Trade Representative (USTR) in 2006, because of unfulfilled commitments under the IPR chapter of the FTA. In 2007, USTR determined Chile had failed to comply with its IPR obligations and placed it on the PWL. Chile has remained on the PWL since that time, with some progress made on its commitments in those two years. Chile's inclusion in the PWL has raised public awareness about IPR problems in the country. In 2007, it increased GOC efforts to improve IPR protections.

ANTI-PIRACY OR COUNTERFEITING: Progress Made  
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¶3. (SBU) The GOC stepped up efforts to combat piracy and counterfeiting in 2008. In January, it created a special 12-person brigade within the Chilean investigative police force to handle intellectual property crimes (BRIDEPI). In its first year of operation, the brigade made more seizures of pirated or counterfeit products than were made in all of 2007 by regular Chilean law enforcement. Between March and July, the GOC organized a public anti-piracy campaign, which included fines for those who were found purchasing pirated or counterfeit products.

¶4. (SBU) Despite GOC efforts, piracy and counterfeiting remain a significant problem. Pirated films, music, and software are relatively easy to find. In November 2008, the upper house of the Chilean Congress (Senate) approved a draft Illegal Commerce Law. The Senate's version of the legislation must now be approved by the lower house (Chamber of Deputies) before it becomes law. The draft legislation includes a variety of measures including: tougher fines for buyers or sellers of pirated/counterfeit products, making it easier to shut down suspected markets of pirated/counterfeit

products, and extending these protections to industrial property.

#### DATA PROTECTION AND PATENT LINKAGE: Limited Progress

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15. (SBU) In 2008, Chile made limited progress on data protection and patent linkage. Chile passed a law in April 2008 creating the new National Institute for Industrial Property (INAPI), which commenced operations in January 2009. INAPI replaced the old Department of Industrial Property (DPI), which had been a part of the Ministry of Economy. INAPI is a regulatory and enforcement authority in charge of all administrative actions related to industrial property registration and protection, including patents and trademarks.

16. (SBU) Despite the creation of INAPI, patent problems continued especially in Chile's pharmaceutical sector. Approvals are still granted for Chilean pharmaceuticals that violate existing patents. The GOC continues to allow local companies to use exclusive company data from Asian, European, and North American companies as the scientific basis for granting approval for the generic copies. The Institute of Public Health (ISP), Chile's version of the FDA, issues a "sanitary" approval which in effect is also a marketing approval. International pharmaceutical companies continue to cite violations of exclusive company test data in the Chilean drug approval process.

17. (SBU) Chile has not established linkage between granting market access and the existence of valid patents. The GOC maintains that linkage is provided through the judicial system, which international pharmaceutical companies perceive is problematic in protecting valid patents. The GOC states that the issue of linkage is subject to interpretation of the obligations under the U.S.-Chile FTA. One notable court case that upheld a patent violation was in 2007. However, the case was not resolved quickly, the resulting fine was minimal, and sales of the drug at issue were never suspended. In 2008, the GOC claimed it shut down a domestic laboratory over patent concerns, but the details of the case remain unclear.

18. (SBU) The Ministry of Health is still considering new rules that would modify Supreme Decree 153, which regulates how the ISP can enforce data protection. The Ministry posted the draft regulations on its website for comment between April and July 2008. One significant proposal would prevent the use of data published by a foreign government's regulatory agency in the patent application of a generic pharmaceutical in Chile. Post knows of at least one incident in which an international pharmaceutical company reported that a Chilean laboratory had successfully used the international company's proprietary data (which the U.S. FDA published on its website) in the Chilean laboratory's patent application.

19. (SBU) By February 2009, the draft rules to modify Supreme Decree 153 had not yet been approved. The Ministry of Health proposed changes to the draft rules in February. One suggested change would have eliminated the protection of proprietary data published by foreign governments' regulatory agencies (described above). This proposal was reportedly rejected, but it remains unclear which of the suggested changes were approved. Once the Ministry of Health has a final text for the new rules, it must be approved by Chile's Controller General, which assesses the legality of government policies. The rules must then be signed by the President and officially published before they can take effect. International pharmaceutical companies indicated that the draft rules published in April 2008 would mark a step forward, but fell short of comprehensive data protections.

#### COPYRIGHTS AND TRADEMARKS: Some Progress

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110. (SBU) Much of Chile's recent efforts on copyrights and trademarks is reflected in landmark legislation pending approval in Congress since 2007. The law contains many provisions including establishing IPR enforcement penalties and assessing Internet Service Provider liability for IPR violations. By February 2009, the law had passed the Chamber of Deputies but still required Senate approval (it had over 250 proposed amendments). In 2008, the GOC and U.S. carried on a positive and sustained dialogue regarding suggested changes to the law. It remains uncertain to what degree the final version will reflect U.S. suggestions. In December 2008,

the Ambassador met with members of Congress, the Minister in charge of the Presidency, the trade minister equivalent, and other key actors on IPR. He stressed the importance of fulfilling IPR obligations under the FTA and speeding passage of pending IPR legislation. His meetings received a positive response, and members of Congress and the Minister in charge of the Presidency agreed to examine moving IPR legislation more rapidly.

SUPPORTING LEGISLATION: Progress Made

¶11. (SBU) Under the IPR chapter of the U.S.-Chile FTA, Chile is obliged to ratify or accede to several key international forums or treaties (e.g., Patent Cooperation Treaty). This requires the appropriate legislation for ratification or accession, for which the FTA defines a precise timeframe. The Chilean Congress approved the Patent Cooperation Treaty (PCT) in October 2008. Passage of the PCT was required by January 2007 under the FTA. The PCT helps coordinate patent recognition between signatories. The GOC also sent two pieces of draft legislation to the Congress in January 2009: a law to ratify the 1991 revisions to the International Convention for the Protection of New Varieties of Plants (UPOV 91) and a law to ratify the Trademark Law Treaty (TLT). Both drafts remain pending in the Congress although passage was required by January 2009 under the FTA.

RECOMMENDATION: Chile Should Stay on the PWL

¶12. (SBU) Chile made limited progress on IPR in 2008. During the December 2008 U.S.-Chile Free Trade Commission, Chile agreed to a 2009 technical review of its IPR obligations under the FTA. Many GOC contacts express their displeasure at Chile's inclusion in the PWL. They reaffirm the need to get off the list. Post concludes that removing Chile from the PWL would eliminate one of the tools in motivating Chile to make progress on its IPR obligations.

SIMONS